



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 17 1998

Rec'd 3/26/98 JB

Mr. Brian W. Devening
President
U.S. Naturals
401 S. Sherman Street
#109
Richardson, Texas 75081

Dear Mr. Devening:

This is in response to your letter of February 3, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that U.S. Naturals is making the following statement for the product US Naturals Revital Tonics Dietary Supplement "Nutritional Support for Menopause:"

"so important for women concerned about the discomforts of menopause"

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate the symptoms of menopause. These claims do not meet the requirements of 21 USC 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 USC 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Dallas District Office, Compliance Branch, HFR-SW140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (file)
HFS-450 (r/f, file, OSN#57077)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:2/10/98
init:GCF-1:LNickerson:3/12/98
f/t:rjm:HFS-456:3/12/98:57077.adv:disc25

U.S. NATURALS™

57077



February 3, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington DC 20204

Notification for Certain Types of Statements on Dietary Supplements

This serves as notification that

US Naturals
401 South Sherman Street
#109
Richardson TX 75081

markets or intends to market dietary supplement products with the following statements:

1. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Revitalizing Formula for Men

Daily Nutrition for Energy and Immunity

high performance tonic to help promote a man's vigor while enhancing immunity.

2. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Nutritional Support for Mental Clarity

contains a treasury of focus-specific nutrients plus Ginkgo biloba, the oldest living plant in the world, which is known to enhance circulation to the brain. This remarkable neuro-enhanced formulation helps support mental clarity, and is ideal for people who have busy, demanding lifestyles, at home or work.

3. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Nutritional Support for Emotional Wellbeing

This relaxing normalizing formulation was developed to help people function contentedly and effectively in the calm manner they desire. At work, at home, it's a natural way to stay centered and emotionally balanced.



4. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Revitalizing Formula for Women

Daily Nutrition for Energy and Immunity

This energizing restorative formula helps renew vitality while enhancing well-being and endurance * help support proper hormonal function and vital well-being.

5. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Nutritional Support for Prostate

may be effective and helpful as support for normal healthy prostate function * for men over 40 who are concerned about prostate health.

6. Brand Name: US Naturals Revital Tonics Dietary Supplement

Name of Dietary Supplement: Nutritional Support for Menopause

so important for women concerned about the discomforts of menopause.

I certify that the information provided in this notice is complete and accurate, and that the above named company has substantiation that the statements are truthful and not misleading.

Signed,

Brian W. Devening

Brian W. Devening
President